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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/471,523 | 12/23/1999 | Richard B. van Breemen | 21726/90386 | 7519 |

7590
Barnes & Thornburg
2600 Chase Plaza
10 South LaSalle Street
Chicago, IL 60603

06/03/2002

EXAMINER

FRIEND, TOMAS H F

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1627

DATE MAILED: 06/03/2002

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/471,523

Applicant(s)

BOLTON ET AL.

Examiner

Tomas Friend

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 7-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 7-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

Change of Examiner's Name

The name of the examiner of this application has changed from Thomas Prasthofer to Tomas Friend.

Status of the Application

Receipt is acknowledged of a response to an office action with amendment on 05 March 2002 (Paper No. 14).

Status of the Claims

Claims 1-12 were pending in the present application. Claim 6 was cancelled as per applicants' request in Paper No. 14. Claims 1-5 and 7-12 are pending and are examined on their merits.

Withdrawn Rejections/Objections

1. The objections to claims 8 and 10 over the word "*whereas*" and absence of the word "*and*," respectively, are withdrawn in response to applicants' amendment.
2. The rejections of claims 1-5, 7-10 and 12 under 35 U.S.C. 112, first paragraph (scope of enablement) are withdrawn in response to applicants' amendments.
3. The rejections of claims 1, 4, 5, 6, and 12 under 35 U.S.C. 112, second paragraph, in sections A, B, C, E, F, G, and I in Paper no. 12 are withdrawn in response to applicants' amendments.

Maintained Rejections

The statutory basis for each of the following rejections may be found in a prior office action.

Maintained Rejections – 35 U.S.C. 112, first paragraph

4. Claim 11 remains rejected under 35 U.S.C. 112, first paragraph, (written description) for reasons made of record in Paper No. 12.

Applicants argue that the meaning of “solutions with predetermined characteristics” is clear from the examples in the specification and provides examples of what would contain.

Applicants’ argument has been carefully considered and found not to be persuasive. The claim stands rejected “*as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.*” Applicants claim encompasses a “*set of standard solutions with predetermined characteristics*” wherein the characteristics are functioning as a substrate for an enzyme, showing desirable rates of enzymatic catalysis, showing desirable rates of cell permeability or transport, or showing enzymatic activation to reactive or toxic metabolites. These characteristics represent a generic group of standards that includes at least thousands of known enzymes, at least tens of thousands of known substrates, at least tens of thousands of molecules with rates of cell permeability or transport (including transport across membranes of bacterial cells of any type, yeast cells, mammalian cells, insect cells, plant cells, etc), and at least tens of thousands of molecules that can be activated to reactive or toxic metabolites.

Applicants, in order to demonstrate possession of such a generic must include representative examples, which would indicate to one of ordinary skill that applicants had possession of the full scope of the claimed invention at the time of filing. Applicants provide only a small number of drugs and the predetermined characteristics of glutathione adduct formation, absorption into a single cell type, and catabolism by cytochrome P450 in the specification. These representative samples are insufficient to convey to one skilled in the relevant art that applicants possessed kits comprising any number of solutions comprising any or all compositions with any predetermined characteristics.

Maintained Rejections – 35 U.S.C. 112, second paragraph

5. Claims 1, 3, and 8 remain rejected under 35 U.S.C. 112, second paragraph, for reasons made of record in Paper No. 12. (section headings from the original rejections are used for consistency).

D. Claim 3 remains rejected over the use of the term “*compound*” (singular) to describe “*a combinatorial library*,” “*a drug mixture*,” “*a mixture of xenobiotic compounds*,” or “*a mixture of endogenous compounds*” (all pluralities).

Applicants argue that the “*compound*” may be “*a single substance or a group of substances*.” One reading the claim however, would clearly interpret the preamble to limit the compound to a single compound. If applicants want to claim “*a compound or compounds*,” this must be made clear by eliminating the conflict (in terms of number) between terms in the preamble and the remainder of the claim.

H. Claim 8 remains rejected over citing the broad recitation “*atmospheric gasses*” as well as “(oxygen and carbon dioxide),” which is a narrower statement of the range/limitation.

Applicants did not traverse this rejection in Paper No. 14.

Claims Rejections – 35 U.S.C. 102

6. Claims 1-5, and 7-11 remain rejected under 35 U.S.C. 102(e) as being anticipated by Venton et al. U.S. Patent 5,872,015 February 1999 for reasons made of record in paper No. 12.

Applicants argue that, in the present application, the amount of compounds in the ultrafiltrate are measured, and cites the specification, pages 14 and 15. Applicants’ argument has been carefully considered and found not to be persuasive. Applicants are arguing limitations that are not found in the rejected claims.

Applicants argue that the present method requires quantitative measurements and cell permeability studies not found in the Venton et al. reference. Applicants’ arguments have been carefully considered and found not to be persuasive. The rejected claims do not include a limitation to quantitative measurement (qualitative comparisons, for example, are encompassed

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by the rejected claims), nor are the claims limited to cell permeability studies, which is one of a list of characteristics recited in claims 1 and 11.

Applicants argue that the Venton et al. method uses “*predetermined target molecules in solution*” while the present invention “*can involve living cells or microsomes which are not in solution.*” Applicants’ arguments have been carefully considered and found not to be persuasive. The rejected claims recite no limitations regarding cells or microsomes.

Applicants argue that the Venton et al. reference “*does not mention enzymes or metabolism.*” Applicants’ arguments have been carefully considered and found not to be persuasive. The rejected claims recite no limitations to enzymes or metabolism. Furthermore, column 19, lines 54-63 of the cited reference lists a number of enzymes that are encompassed by the term “*receptor*” as used in the reference.

Maintained Rejections - 35 U.S.C. 103

7. Claim 12 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Venton et al. U.S. Patent 5,872,015 February 1999 for reasons made of record in Paper No. 12.

Applicants argue that the parallel arrangement of chambers with a single mass spectrometer for high throughput screening is unique to the claimed invention and that no publication has been cited to indicate that it would be obvious to use such an arrangement. Applicants’ arguments have been carefully considered and found not to be persuasive. The relevant part of the rejection made in Paper No. 12 reads:

“The teachings of the Venton et al. reference are described in the preceding rejections under 35 U.S.C. 102(e). The Venton et al. reference does not teach multiple chambers with ultrafiltration arranged in parallel with a single mass spectrometer.

It would have been obvious to one of ordinary skill in the art at the time that the invention was made to arrange multiple chambers with ultrafiltration (membranes) in parallel with a single mass spectrometer. One would have been motivated to do so in order to scale up the volume of samples that could be assayed at one time. One would have had a reasonable expectation for success because high throughput mass spectrometry capable of handling large numbers of samples was routine in the art.”

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Applicants argue that it would not be obvious, to one of ordinary skill in the art at the time that the invention was made, to use two of the devices taught in Venton et al. with the method of Venton et al. instead of one in order to double the number of assays that could be performed at one time. The examiner maintains that doubling the number of devices to increase the number of samples being screened is an obvious modification of the Venton et al. method.

New Grounds of Rejection

The statutory basis for each of the following rejections may be found in a prior office action.

New grounds of Rejection – 35 U.S.C. 112, second paragraph

8. Claim 1 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. In claim 1, the metes and bounds of the phrase “*screening for metabolic parameters*” are not clear. One of ordinary skill in the art would not know what the metes and bounds of “*metabolic parameters*” are because the term is not defined in the specification in such a way that the one could determine what is encompassed by or excluded from “*metabolic parameters*.”

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Tomas Friend** at telephone number **(703) 308-4548**. The examiner can normally be reached on Monday, Tuesday, Friday, and Saturday 8:00-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat can be reached on (703) 308-2439. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-2742.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist at (703) 308-1235.

Tomas Friend, Ph.D.
28 May 2002


DR. JYOTHSNA VENKAT PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600